UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
VICINAGE OF TRENTON

HANNAH LOVAGLIO, J.L. and **B.L.**, by next friend, Hannah Lovaglio, **ERICA JEDYNAK**, **JEREMIAH JEDYNAK**, and **C.J.**, by next friends, Erica and Jeremiah Jedynak, *Plaintiffs*, v. **KAITLAN BASTON**, Commissioner of the New Jersey Department of Health, sued in her official capacity, and **NANCY SCOTTO-ROSATO**, Assistant Commissioner for the Division of Family Health Services, sued in her official capacity, *Defendants*.	Hon. Georgette Castner, U.S.D.J. Hon. Rukhsanah L. Singh, U.S.M.J. Civil Action No. 3:23-cv-21803

DEFENDANTS' BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

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PRELIMINARY STATEMENT

All 50 States screen infants born within their borders for an array of congenital disorders that, if not detected promptly, can cause lifelong harm or death. N.J. Stat. Ann. § 26:2-110(a); First Am. Compl. (FAC), ECF 31, at ¶ 2. They do so by having hospital staff collect a few spots of blood on a filter-paper card, which the hospital then sends to a public-health lab, which analyzes one or more of the spots. *Id.* ¶¶ 17-18. In New Jersey, this initial process generally concludes within two weeks; after that, any parent who wants the remaining spots destroyed can do so by emailing a simple form. *See id.* ¶¶ 90-91. Under a new policy announced by New Jersey's Department of Health (DOH) this past June, meanwhile, the *default* retention period is two years—at that point, if DOH has not received a request to the contrary, it will destroy the remaining spots. *See id.* ¶¶ 88-89, 98. And during those initial two years of retention, DOH may use the residual spots for only three purposes, unless it obtains informed consent: follow-up testing for the child; quality control (QC) and quality assurance (QA) for DOH; and developing new tests for newborn screening (NBS). *Id.* ¶ 112.

Plaintiffs ask this Court to hold that this public-health policy constitutes an impermissible Fourth Amendment seizure, or alternatively a violation of parents' Fourteenth Amendment rights to control medical decisions about their children. *Id.* ¶¶ 156-199. But in doing so, they seek a rule under which every single State's

retention policy would be unconstitutional. That is because no State, as far as New Jersey has been able to identify, does what Plaintiffs demand: destroys residual blood spots, if they have not received an affirmative request to keep them, as soon as the child turns two weeks old. For good reason: retention provides crucial benefits to the child, the family, and society as a whole, all non-intrusively. Further, the default-destruction model that Plaintiffs demand would work asymmetrical harms: if a parent fails to request retention within those first two weeks (or the hospital misplaces the request), destruction is irreversible, whereas a parent who belatedly seeks destruction can, of course, obtain it. And while many States do not permit parents to "opt-out" of retention after initial screening, New Jersey does—so no parent must submit to retention against their wishes. *See id.* ¶¶ 90-91.

Plaintiffs' outlier quarrels with this public-health program lack merit, and both their Fourth and Fourteenth Amendment claims should be dismissed. Initially, Plaintiffs lack standing because the injuries they allege are not fairly traceable to the State—they are easily avoidable by requesting destruction. And to the extent Plaintiffs speculate about how DOH could "possibly use" the blood spots in nefarious ways, FAC ¶ 76, that conjecture falls far short of what Article III requires.

In any event, Plaintiffs also fail to state a Fourth Amendment claim. For one, there is no "seizure"—Plaintiffs have no possessory interest in the spots left over from a heel prick authorized by law and unchallenged in this suit, much as a patient

does not retain property rights in a nasal swab left over after a Covid-19 test. That explains why Plaintiffs would accept DOH simply destroying all the blood spots in the NBS program—including millions belonging to people whose preferences they do not know. *See* FAC ¶ 141. In any event, any putative seizure is plainly reasonable under the special-needs exception to the warrant requirement, which is tailor-made for a program like this one, which serves public health rather than law enforcement purposes. Under the requisite balancing test, the degree to which the program serves the State's public-health interests dramatically outweighs any intrusion on Plaintiffs' interests—a putative intrusion, moreover, that can be avoided simply by asking.

Plaintiffs' due process claim gets no further. Put simply, nothing about DOH's default two-year retention burdens a parent's right to direct their child's upbringing or medical care. Whether construed as a failure to state a claim or a failure to show an injury-in-fact (or both), this claim likewise fails as a matter of law.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

A. Newborn Screening In The United States.

"Newborn screening is an essential public health activity that strives to screen every newborn infant for a variety of congenital disorders, which, if not detected and managed early, can result in significant morbidity, mortality, and disability." N.J. Stat. Ann. § 26:2-110(a); *see also* CDC, *About Newborn Screening*,

https://www.cdc.gov/newborn-screening/about/index.html.[1] Newborn screening (NBS) is also "not particularly controversial—every state does it." FAC ¶ 2. Such "programs date back to the early 1960s when newborn screening was created to test infants for phenylketonuria (PKU)," a genetic disorder that prevents the body from breaking down phenylalanine, but that can be wholly mitigated with early detection. *See* Barraza & Burkhart, *The Expansion of Newborn Screening: Implications for Public Health and Policy*, 23 Annals Health L. 183, 184-85 (2014). Today, all 50 States conduct NBS, with every State testing for at least 29 recognized disorders (including PKU). *See id.* at 187. The Federal Government has also long been involved in supporting State NBS programs. *See, e.g.*, 42 U.S.C. § 300b-10(b)(8)(G).

NBS follows the same general process in every State: shortly after birth, a few drops of blood are collected on a filter-paper card by a hospital nurse via a "heel prick." *E.g.*, FAC ¶¶ 2, 17. In the days following, a public-health lab tests one or more of the dried blood spots (DBS) on the filter-paper card for a panel of disorders. *E.g.*, *id.* ¶ 18. This "initial screening" generally involves measuring "biomarkers" in the baby's blood and comparing them to cut-off values set by researchers, to check whether these biomarkers are in a normal range for the relevant patient population. *See, e.g.*, Minn. Dep't of Health, Newborn Screening Information for Providers,

[1] This Court can consider undisputed government sources and "legislative facts" in evaluating this motion to dismiss. *See, e.g.*, Fed. R. Evid. 201(a); *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010).

https://tinyurl.com/3m547ve5. The initial-screening process typically concludes within one to two weeks. *E.g.*, FAC ¶ 166; Barraza & Burkhart, *supra*, at 184.

Each State retains the residual dried blood spots (rDBS) for some time after initial screening. That initial-retention period varies, from 90 days to indefinitely.[2] Texas and Connecticut, for example, set the default period at two years—as New Jersey now does too.[3] The length of initial retention can depend on various factors, including the diseases tested for, the extent to which the State makes follow-up testing available, and whether a State does its own testing or outsources it.

During this initial period, residual spots are typically used (if at all) for follow-up testing (*e.g.*, to test whether there has been a "false positive" or "false negative"); to ensure the integrity of the NBS program through QA and QC; and to develop and

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[2] *Compare, e.g.*, 181 Neb. Admin. Code § 2-001 (90 days); Tenn. Code Ann. § 68-5-406 (1 year); Alaska Div. of Pub. Health, *Newborn Bloodspot Screening* (Apr. 5, 2016) https://tinyurl.com/ba9kuu7n (3 years); Iowa Admin. Code r. 641-4.3 (5 years); Mo. Rev. Stat. § 191.317 (5 years), *with* Md. Code Regs.10.10.13.15 (25 years); 10-144 Code of Maine Rules c.283, § 12 (indefinite).

[3] *See* Tex. Health & Safety Code Ann. § 33.0112; CT.gov, *The Conn. Newborn Screening Program: Frequently Asked Questions*, https://tinyurl.com/ymwwbywd. Some States retain residual blood spots that tested positive for a longer period than those that tested negative. *See, e.g.*, Ill. Admin. Code tit. 77, § 661.220; https://www.vdh.virginia.gov/dried-blood-spot-newborn-screening/retention-of-residual-dried-blood-spots/; FAC ¶ 83. Although some States allow parents to receive a sample of their newborn's blood for future emergencies, *e.g.*, FAC ¶ 106, this does not replace the collection and retention performed. *Compare* Va. Code Ann. § 32.1-134.02, *with* Va. Code Ann. § 32.1-65.

validate tests for new diseases. *E.g.*, FAC ¶ 112; Tenn. Code Ann. § 68-5-406. Some States allow parents or legal guardians[4] to obtain destruction of the residual spots during this period, *e.g.*, Mo. Title XII, § 191.317(2); Montana Dep't of Pub. Health and Human Servs., *Parental Request for Destruction of Newborn Screening Sample*, https://tinyurl.com/39xz5ehu; FAC ¶¶ 90-91, while others do not, *e.g.*, S.C. Code Ann. § 44-37-30; CT.gov, *supra* at 5 n.3. To DOH's knowledge, no State has ever adopted the system that Plaintiffs in this lawsuit demand: one in which this initial retention is barred unless parents affirmatively request it.[5] Indeed, many States do not allow parents to opt-*out* of initial retention (though New Jersey does).

B. New Jersey's NBS Program.

Since 1964, New Jersey has performed newborn screening "to protect the health and quality of life of newborn infants born in this State" by providing "all newborn infants with screens for certain conditions and with appropriate referrals."

[4] This motion uses the word "parents" as shorthand for both, intending no disrespect.
[5] Only one State has been forced to adopt anything approaching such a system—Michigan, after a district court opinion that is now on appeal in the Sixth Circuit. *See Kanuszewski v. Mich. HHS*, 684 F. Supp. 3d 637, 660 (E.D. Mich. 2023), *appeal pending*, 6th Cir. No. 23-1733 (filed Aug. 16, 2023). That decision also came in the context of Michigan's BioTrust for Health research program and Neonatal Biobank, which the district court found to have facilitated significant third-party research. 684 F. Supp. 3d at 643-44. It is not clear that Michigan is currently requiring affirmative consent for the only three uses that New Jersey's program allows: (1) follow-up testing; (2) QA/QC; and (3) new-test development. *See* Michigan BioTrust for Health, *Newborn Consent Form*, https://tinyurl.com/yfzc6z7j (noting that rDBS will still be used for QC/QA even if the parents refuse to consent to research); FAC ¶ 89.

N.J. Stat. Ann. § 26:2-110(c). While newborn screening is universal across States, FAC ¶ 2, New Jersey's program is particularly comprehensive, screening all infants born in the State for 61 disorders. *See* N.J. Admin. Code § 8:18-1.3.

Absent a parental objection on religious grounds, FAC ¶ 27, all babies born in New Jersey have a blood sample taken via heel prick within 48 hours of birth. Pursuant to changes to the program announced on June 20, 2024—for which DOH is in the process of promulgating regulations expected to be published for notice and comment in December 2024—all parents will receive a revised information card at the time of the heel prick. As relevant, this informational card explains that (1) parents may opt-out of initial retention at any time; (2) absent a destruction request, any rDBS linked with a child's identifying information will be retained only to the two-year mark; and (3) during initial retention, DOH will use the residual spots only for follow-up testing, QA/QC, and new-test development. FAC ¶¶ 87-92. This card contains a QR code that parents can use to obtain more information, as well as to access the destruction-request form (which they can submit by email). *Id.* ¶¶ 89-90.[6]

After the heel prick, the filter-paper card containing the blood spots is sent to DOH's NBS Laboratory (Lab), where Lab staff test one or more of the spots from the card, comparing the sample's biomarkers to the cut-off values indexed to the

[6] *See also* DOH, Sample Parent NBS Informational Card (Nov. 1, 2024), https://www.nj.gov/health/phel/documents/Parent-Information-about-NBS-Specimen-Retention.pdf (high-resolution version of green card at FAC ¶ 89).

Lab's patient population. *Id.* ¶ 2; N.J. Admin. Code § 8:18-1.4(a); *id.* § 8:18-1.9(a)(3). Results are communicated promptly to the baby's doctor, and DOH staff follow up further with the doctor (or family) of any newborn whose results are "positive"—*i.e.*, in the abnormal range for the patient population. *Id.* §§ 8:18-1.9(a)(4)-(5), -1.10. Per the new policy, any spots linked to a child's information are destroyed at the two-year mark unless a parent requests shorter or longer retention. FAC ¶¶ 83, 89.[7] For positive samples, the Department will separate identifying information from the sample and retain one *de-identified* spot for up to ten years. *Id.*

As noted, DOH may only use the residual spots for three purposes during retention unless it receives express parental consent: (1) follow-up testing; (2) QA/QC; and (3) new-test development. *Id.* ¶ 89. As discussed more below, these three purposes serve the individual baby and its family by enabling the Lab to catch "false negatives" or "false positives." *See infra* at 27-31. They also serve future children, by helping the Lab to improve its existing tests (*e.g.*, to adjust its cut-off

[7] Parents can, as noted, obtain destruction on request after initial testing, FAC ¶¶ 89-90, and can also obtain longer retention (up to a total of 10 years) by submitting a separate form, DOH, *Public Notice of Change to Newborn Screening Program's Retention Policy* (Jun. 20, 2024), https://nj.gov/health/phel/documents/newborn-screening-retention-policy.pdf (DOH Notice); DOH, *Use, Retention, and Destruction of Newborn Screening Program Dried Blood Spots* (Nov. 1, 2024), https://www.nj.gov/health/phel/documents/NJ-NBS-Blood-Spot-Use-Policy-Effective.pdf (New Policy).

levels to better serve its patient population) and to develop new ones (whether by using existing biomarkers or figuring out new ones to look for). *See infra* at 30-32.

The Lab may not, meanwhile, release rDBS linked with a child's identifying information to any non-law-enforcement third party without express consent. FAC ¶ 89; New Policy. These limits are consistent with significant restraints already imposed by state and federal law. For instance, the NBS statute mandates that information related to NBS "shall be confidential and not divulged or made public so as to disclose the identity of any person to which it relates, except as provided by law." N.J. Stat. Ann. § 26:2-111; *see also* N.J. Admin. Code § 8:18-1.13. No provision permits the selling of blood spots, or transferring identified rDBS to any private party without express consent. Indeed, any research institution that receives federal funding and performs "human subjects research" (such as research on residual blood spots linked to a specific child) must, under federal law, already obtain parental consent for any research to be performed (along with approval from an Institutional Review Board), *see* 45 C.F.R.§ 46.116, and New Jersey has extended these requirements to all research institutions, federally funded or not, *see* New Policy. Only de-identified blood spots—which cannot be linked back to an identifiable child, and thus pose no privacy risk—can be used for research without such affirmative, informed consent.

The Lab may release residual blood spots linked with a child's identifying information to law enforcement, meanwhile, only with express consent, or where obligated to do so by legal process obtained consistent with a new Attorney General Directive. *See* N.J. Att'y Gen. Law Enf't Directive 2024-03 (Jun. 20, 2024), https://tinyurl.com/ye2ajt2r (AG Directive).[8] Such instances were already "exceedingly rare," *see id.*—over 100,000 babies benefit from NBS in New Jersey each year, FAC ¶ 19, and Plaintiffs have alleged only five occasions in which residual spots were provided to law enforcement, FAC ¶ 49.[9] Such rare occurrences should become even rarer now that the default retention period has been reduced to two years,[10] and moreover given that Directive 2024-03 adds further limits to law enforcement's ability to even *seek* access to rDBS. *See* AG Directive. Specifically, such agencies must request approval in writing from the State, explaining why theirs is "an exceptional circumstance that necessitates seeking information from the

[8] In other words, DOH will not voluntarily share residual blood spots with law enforcement—it will do so only when required to by a validly obtained legal order.

[9] The FAC does not allege that each of these five occasions were used to build a criminal case against someone, *see* FAC ¶ 49, and it is equally plausible that most were used, for example, to identify a victim, *see* AG Directive (reserving this potential use). The State is aware at this time of only one such instance involving use of a residual spot to identify a crime suspect, involving a case of sexual assault.

[10] The State is in the midst of implementing the New Policy. At the end of the month, for example, the State Records Committee will meet to formalize the decrease in the default retention length from 23 years to two years. Similarly, DOH is in the process of procuring a vendor to destroy existing samples that are more than two years old.

[NBS] Program and why less intrusive means will not suffice." *Id.* Further, even if they receive approval, agencies may only obtain such information if they can also obtain one of three forms of "appropriate legal process:" (1) a search warrant based on probable cause; (2) a court-issued *Dyal* subpoena, which "is the functional equivalent of a search warrant" in New Jersey medical-records cases, *see State v. Dyal*, 478 A.2d 390, 396 (N.J. 1984); or (3) in tragic (non-prosecution-oriented) instances, pursuant to an administrative subpoena to help identify a missing person or unidentified body under N.J. Stat. Ann. §§ 52:17B-9.7 to -9.8d. *See* AG Directive.

C. This Lawsuit.

In November 2023, three parents (Parent-Plaintiffs, or Parents), individually and on behalf of three minor children (Child-Plaintiffs, or Children), filed a putative class action against the Commissioner of DOH (Commissioner) and the Assistant Commissioner for the Division of Family Health Services[11] in their official capacities, challenging as unconstitutional DOH's retention policy for residual blood spots, which at the time lasted 23 years. ECF 1. Plaintiffs correctly acknowledged as "not particularly controversial" the initial blood draw and testing, *e.g.*, ECF 1 at ¶ 2, instead challenging DOH's *retention* of the residual spots absent a parental

[11] For comprehensiveness, DOH notes that the Assistant Commissioner is not a proper defendant: neither she nor her office receives, maintains or stores blood spots. *Cf. Chavarriaga v. N.J. Dep't of Corr.*, 806 F.3d 210, 223 (3d Cir. 2015) (plaintiff must demonstrate that official had personal involvement or otherwise "established or enforced policies and practices directly causing the constitutional violation").

request for destruction, *see, e.g.*, *id.* ¶ 6. They alleged that this retention violated both the Children's Fourth Amendment rights against unconstitutional seizures (Count I), and the Parents' Fourteenth Amendment substantive due process rights to oversee the care, custody, and control of the Children (Count II). *Id.* ¶¶ 106-143. Plaintiffs did not (and have not) requested that DOH destroy the residual spots associated with their children, and have never disputed that DOH would promptly do so if asked.

The parties engaged in settlement discussions that ultimately were not productive. DOH made significant changes to the program anyway, issuing a notice in June 2023 explaining that, as of November 1, the default retention period would (as detailed above) be shortened two years for all negative samples (with positive samples subject to a slightly different regime whereby one spot would be de-identified and retained for ten years[12]), and with all parents given the option to obtain extended retention up to ten years by requesting it. *See* FAC ¶¶ 83, 95-96; DOH Notice. DOH, in the process of implementing this new policy, provided Plaintiffs (and publicly posted) information about the new program, such as the new "green card" that hospitals would be mandated to provide to parents at the time of the heel prick. *See* FAC ¶ 89. This card explains how parents can obtain destruction by emailing a simple form, and lays out the only uses (follow-up testing, QA/QC, new-

[12] Because Plaintiffs allege that their Children's screens luckily "came back as normal," FAC ¶¶ 57, 70, this policy for positive samples is not before this Court.

test development) to which DOH can put residual spots during the default two-year period if parents decline to request destruction. *See* FAC ¶¶ 89, 112. The Attorney General also issued Directive 2024-03, restricting the circumstances under which law enforcement may seek residual blood spots. *See supra* at 9.

The Court held a pre-motion conference in July 2024, ECF 29, and on August 2, Plaintiffs filed their FAC, ECF 31. Like Plaintiffs' initial complaint, the FAC challenges only the default retention period (now two years), arguing that DOH may not set a default of retention, and instead must destroy residual spots after two weeks absent an express request otherwise. *E.g.*, FAC ¶ 93. Plaintiffs do not allege (nor could they) that any State has ever adopted such a system. *See supra* at 6.

As before, Plaintiffs allege both Fourth Amendment claims on behalf of the Children (Count I) and Fourteenth Amendment substantive due process claims on behalf of the Parents (Count II). FAC ¶¶ 156-199. They ask this Court to certify them to represent a class of potentially "*millions*" of children and parents, *see id.* ¶ 141, and to enjoin DOH from retaining any residual blood spots—including the millions that have nothing to do with their Children—in the absence of an express request for retention. *Id.* ¶ 177. Absent such a request, Plaintiffs ask this Court to order the State to "destroy" or "return" all residual spots "within a year." *E.g.*, *id.* ¶¶ 177, 179.

DOH now brings this motion to dismiss under Rule 12(b)(1), (6). *See* ECF 33.

ARGUMENT

I. PLAINTIFFS LACK STANDING.

"Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.'" *Murthy v. Missouri*, 144 S. Ct. 1972, 1985 (2024). "A proper case or controversy exists only when at least one plaintiff … show[s] that she has suffered, or will suffer, an injury that is concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Id.* at 1985-86 (cleaned up). Plaintiffs "bear[] the burden of establishing these elements." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). They cannot do so. As a brief initial matter, they lack standing to challenge DOH's policy as to *positive* samples, as Plaintiffs allege only negative results, and thus cannot litigate on behalf of children who tested positive. *See id.*; FAC ¶¶ 57, 70. But more centrally, even as to default retention of negative results, Plaintiffs cannot show standing because they cannot establish traceability. And to the extent Plaintiffs rely on risks they fear *might* come to pass, their claims are purely speculative.

A. Plaintiffs Cannot Show Traceability.

To satisfy the traceability element of standing, a plaintiff must establish that her injury "likely was caused … by the defendant's conduct." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). This requirement "is central to Article III standing," *id.* at 383, and ensures that Plaintiffs "cannot manufacture standing

merely by inflicting harm on themselves" and then blaming the government. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 416 (2013). Such "self-inflicted" injuries are insufficient to satisfy Article III. *Id.* at 418.

Claims often fail based on a plaintiff's failure to take simple action to avoid a result they seek to challenge. Take a well-known example: unwanted telemarketing calls. Consumers are entitled to protection from these calls, but they have to do something first: request to be placed on the do-not call registry. If a consumer fails to do that, he cannot blame the telemarketer—the alleged injury is traceable to his own omission, not the telemarketer's action. *Cordoba v. DIRECTV, LLC*, 942 F.3d 1259, 1271-72 (11th Cir. 2019); *see also, e.g.*, *Zimmerman v. City of Austin*, 881 F.3d 378 (5th Cir. 2018) (plaintiff did not have standing to challenge campaign financing law because his injury was self-inflicted; he could have simply not accepted donations that put him over the limit). Just as a parent who objects to NBS on religious grounds could not decline to invoke the statutory exception, N.J. Stat. Ann. § 26:2-11, and then blame the State, parents who can easily avoid retention by opting out of this default policy cannot properly fault the policy itself.

This blackletter concept has already been applied in this very context, with courts recognizing that plaintiffs lack standing where residual blood spots are retained only because parents decided not to request destruction. *See Doe v. Adams*, 53 N.E.3d 483, 498 (Ind. Ct. App. 2016) (child-plaintiff in Fourth Amendment

challenge to retention of residual blood spots lacked standing because her "parents could at any time request that her DBS sample be destroyed"); *Higgins v. Texas Dep't of Health Servs.*, 801 F. Supp. 2d 541, 553 (W.D. Tex. 2011) (plaintiffs in Fourth Amendment challenge to retention of blood spots lacked standing because "there is no allegation that … they requested that the blood specimens be destroyed"). The same is true here: Plaintiffs cannot make a federal case of DOH's retention of rDBS associated with their children when the only reason those spots have been retained is that the Parents have chosen not to request destruction. *See* FAC ¶ 89. After all, Plaintiffs recognize that DOH's policy permits any parent to obtain destruction "at any time after initial testing," *id.*; *see id.* ¶¶ 90-92, and have never disputed that DOH would promptly do so if asked. The Parents' failure to request destruction renders the retention they complain of "self-inflicted" and thus precludes them from invoking Article III jurisdiction. *See Clapper*, 568 U.S. at 418.

Nor is this a formalistic objection. The "causation requirement" does crucial work: it "screens out" plaintiffs who would like to litigate against the government because they have a "strong moral, ideological, or policy objection to" what the government is doing, but are not actually suffering any injury traceable to government action. *All. for Hippocratic Med.*, 602 U.S. at 382-83. Here too, while Plaintiffs have every right to believe that "keeping the blood of an innocent newborn, who has done nothing wrong, is immoral," FAC ¶ 75, their actions are what matter

for purposes of Article III: by declining to simply request that DOH destroy the relevant blood spots, they are effectively bringing the alleged harm "on themselves," *Clapper*, 568 U.S. at 416. Because that harm is not fairly traceable to DOH, there is no true Article III case or controversy—only a "manufacture[d]" one. *See id.*

B. Plaintiffs' Invocations Of Alleged Risks Are Unduly Speculative.

Plaintiffs' FAC at times appears to try a different tack: suggesting harms they fear *may* befall them from hypothetical uses of rDBS. To the extent they ground their claims in those concerns, there is a different Article III problem: no injury-in-fact.

To satisfy Article III's injury-in-fact requirement, a claimed injury "must be actual or imminent, not speculative—meaning that the injury must have already occurred or be likely to occur soon." *All. for Hippocratic Med.*, 602 U.S. at 381; *see also Sherwin-Williams Co. v. Cnty. of Delaware*, 968 F.3d 264, 269 (3d Cir. 2020) ("Allegations of possible future injury do not satisfy the requirements of Art. III. A threatened injury must be 'certainly impending' to constitute injury in fact." (citation omitted)). This hornbook rule has also come up in this context, and every court that has addressed such hypothetical concerns has held that they are insufficient to confer standing. Thus, in *Kanuszewski*, the plaintiffs argued in part that the Michigan defendants could sell, transfer, or otherwise "misuse" the children's blood spots. *Kanuszewski v. Mich. Dep't Health & Human Servs.*, 927 F.3d 396, 409-10, 409 (6th Cir. 2019). In its ruling on the matter, however, the Sixth Circuit held that, because

this "theory of harm consists largely of speculation," it "cannot satisfy the injury-in-fact requirement" of standing. *Id.* at 410.[13] Similarly, in *Doe*, plaintiff alleged that her blood spots were subject to "misappropriation" or other potential "misuse." *Doe*, 53 N.E.3d at 497-98. The Indiana court, however, held that "Doe's fear of potential misuse is … 'speculative,' and does not constitute the type of direct injury necessary to support a finding of standing." *Id.* at 498. Likewise, in *Higgins*, plaintiffs alleged that their children's blood spots might have been "distributed" to third parties and "could be potentially misused in the future." *Higgins*, 801 F. Supp. 2d at 553. The Western District of Texas held that "[s]uch speculation" was "insufficient to demonstrate a real and immediate threat of future injury." *Id.*

The hypothetical risks mentioned in the FAC likewise fall far short of this imminence threshold. *See, e.g.*, FAC ¶ 64 (claiming to have "worries about how New Jersey may be abusing its possession of her children's blood"); *id.* ¶¶ 49, 65 (noting that DOH released residual spots from other children to law enforcement "on at least five occasions" in the past); *id.* ¶ 66 (noting that "other states" have "us[ed] babies' blood in alarming ways"). As Plaintiffs acknowledge, DOH expressly forbids transfer of any residual blood spots linked with a child's identifying information to a private third party without consent. *Id.* ¶ 89. As for concerns about the five

[13] As noted, the Eastern District of Michigan's *final* judgment in *Kanuszewski* is now on appeal. *See* 6th Cir. Dkt. No. 23-1733.

instances in the past in which materials were shared with law enforcement pursuant to grand jury subpoenas (rather than warrants), the likelihood of such an event impacting Plaintiffs was miniscule when they first sued, and even smaller now: for one, default retention is now only two years, and for another, a binding AG Directive ensures that agencies can seek such information only "in genuinely exceptional circumstances," *Id.* ¶¶ 49, 117; *see also* AG Directive (providing that, even then, law enforcement must obtain a warrant or its state-law equivalent, except in circumstances involving missing children or unidentified bodies).[14] And if Plaintiffs are concerned that Texas is "turning over blood to the Pentagon," *id.* ¶ 66, then their quarrel is with Texas. In short, concerns that DOH may "possibly use" retained samples "against the children," *id.* ¶ 76, are as unduly speculative as they are misguided. Such conjecture does not satisfy Article III.

II. PLAINTIFFS' FOURTH AMENDMENT CLAIM FAILS AS A MATTER OF LAW.

Even assuming Plaintiffs have standing, their Fourth Amendment claim fails as a matter of law for two independent reasons. First, Plaintiffs have no possessory interest in residual dried blood spots, or at least not one that would preclude DOH's

[14] Plaintiffs assert that the AG Directive is "non-binding," FAC ¶ 122, but only in the sense that it could be rescinded by a future Attorney General. To be clear, the Directive *is* binding on law enforcement. *See In re Att'y Gen. L. Enf't Directive Nos. 2020-5 & 2020-6*, 252 A.3d 135, 149-50 (N.J. 2021) ("As the Court has recognized on prior occasions, Attorney General directives relating to the administration of law enforcement have the 'force of law.'" (citation omitted)).

retention for the limited purposes at issue. Second, and in any event, DOH's default two-year retention, with destruction available on-demand, is wholly reasonable under the Fourth Amendment's "special-needs" exception, which is tailor-made for a minimally intrusive public-health program like this one, that indisputably is designed to help scientists and doctors detect potentially life-threatening conditions in newborns, not to enforce criminal (or even civil) laws.

A. Default Retention Is Not A Fourth Amendment "Seizure."

The Fourth Amendment protects "personal property" against "unreasonable searches and seizures." *United States v. Place*, 462 U.S. 696, 700 (1983). "A 'seizure' of property occurs when there is some meaningful interference with an individual's possessory interests in that property." *United States v. Jacobsen*, 466 U.S. 109, 113 (1984). Here, the State's retention policy does not even implicate the Fourth Amendment, because Plaintiffs do not have a possessory interest in residual blood spots from a heel-prick draw and initial testing that Plaintiffs do not challenge.

To start, residual blood spots are not Plaintiffs' personal property. "Generally speaking, state law defines property interests." *Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot.*, 560 U.S. 702, 707 (2010); *cf. Brown v. Muhlenberg Twp.*, 269 F.3d 205, 211 (3d Cir. 2001) (looking to Pennsylvania law to assess possessory interests in Fourth Amendment seizure case). Plaintiffs have not identified any basis to treat residual blood spots as personal property under New

Jersey law, and no such basis exists.[15] Instead, they are a kind of medical waste—which is why DOH is permitted to destroy residual spots even without a parental request. *See* N.J. Stat. Ann. § 13:1E-48.3; N.J. Admin. Code § 7:26-3A.6(a), (b)(3). That also helps explain why Plaintiffs—who "are not challenging [the] heel prick or the test itself," FAC ¶ 2—could not bring a Fifth Amendment takings claim.

Nor do Plaintiffs have any other kind of possessory interest in rDBS. As noted, the Fourth Amendment's ban on unreasonable seizures is triggered only if there is a meaningful interference with a person's possessory interests—so no possessory interest, no seizure. *See Soldal v. Cook Cnty.*, 506 U.S. 56, 63 (1992); *U.S. v. Frezzo Bros., Inc.*, 602 F.2d 1123, 1130 n.11 (3d Cir. 1979) (because defendants had no possessory interest in property at stake, they could not contest seizure); *see also, e.g.*, *Dix v. Edelman Fin. Servs., LLC*, 978 F.3d 507, 513 (7th Cir. 2020). A "'[p]ossessory interest'" is the "'present right to control property, including the right to exclude others'" or a "'present or future right to the exclusive use and possession

[15] The New Jersey Legislature has *considered* recognizing property interests in biological information. *E.g.*, Genetic Privacy Act, L. 1996, c. 126, § 7 (First Reprint, adopted Mar. 14, 1996) (initial version of bill would have provided that "[a]n individual's genetic information is the property of the individual," but this language was removed after Governor's conditional veto); A525 § 1 (introduced Jan. 11, 2022) (proposed language would provide that a "DNA sample and the genetic information resulting from a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed"). But it has not done so.

of property.'" *United States v. Dixon*, 901 F.3d 1322, 1338 (11th Cir. 2018) (quoting Black's Law Dictionary (10th ed. 2014)). No such interest exists here.

Indeed, courts have repeatedly recognized that individuals do not retain a possessory interest in bodily fluids or tissues removed from their bodies during an authorized medical procedure. Take the seminal case of *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990) (en banc), in which doctors performed a splenectomy on a patient suffering from hairy-cell leukemia. *Id.* at 480-81. The cells they obtained were scientifically valuable, *id.* at 481-82, and the patient later sued, claiming he had "possessory and ownership interests" in "his cells following their removal from his body," *id.* at 487. The California Supreme Court rejected his claim, explaining that no case had ever held "that a person retains a sufficient interest in excised cells." *Id.* at 489. The high court did "not find this surprising, since the laws governing such things as human tissues … [and] blood" treat such "biological materials as objects sui generis," not as "personal property." *Id.*; *see also Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 988, 997 (E.D. Mo. 2006) (holding that research university, not donor, owned "prostate tissue, blood, and DNA samples" removed from research participants); *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003) (holding that individuals "have no cognizable property interest in body tissue and genetic matter donated for research"); *State v. LaRosa*, 179 N.E.3d 89, 95 (Ohio

2021) (holding that criminal defendant could not claim a "possessory interest in … urine that ended up on a [hospital] washcloth").

That fits with common sense. After all, few would argue that a patient retains a possessory interest in the blood left on gauze used to dab his arm after a routine blood test, or mucus left on the nasal swab after a Covid-19 test. Here too, the State's authority to conduct the heel prick and initial testing is unchallenged; Plaintiffs recognize that initial screening is "not particularly controversial" and "every state does it." *See* FAC ¶ 2. Consistent with these precedents, Plaintiffs do not then retain a possessory interest in the residual blood spots left on the filter paper.[16]

The FAC underscores the point. After all, Plaintiffs readily concede that the State can permissibly destroy residual spots, and indeed they seek an order to that effect—one that would govern well over 100,000 families they have never met. FAC ¶¶ 177(c), 179(c). But if Plaintiffs were correct that all of these families retain a possessory interest, then they would be inviting the State (and this Court) to engage in a violation of a great many of those individuals' alleged property rights by requiring the samples to be destroyed. That they welcome widescale destruction as the default proves the logical inconsistency in their own claims.

[16] Importantly, this case presents only a claim against DOH officers. If a defendant were ever to face prosecution using evidence from residual blood spots, that defendant could litigate a putative possessory interest to exclude *law enforcement* at that time—presumably by moving to suppress. *See also infra* at 35-37.

Nor can Plaintiffs cure this legal defect by invoking generalized privacy interests, because they challenge a *seizure*, not a search. *See* FAC ¶¶ 164-74. The distinction matters: "[t]he interest protected by the Fourth Amendment injunction against unreasonable searches is quite different from that protected by its injunction against unreasonable seizures." *Arizona v. Hicks*, 480 U.S. 321, 328 (1987). A search "occurs when an expectation of privacy that society is prepared to consider reasonable is infringed"; a seizure, by contrast, "occurs when there is some meaningful interference with an individual's possessory interests in that property." *United States v. Jacobsen*, 466 U.S. 109, 113 (1984); *see also United States v. Miller*, 799 F.3d 1097, 1102 (D.C. Cir. 2015) ("It is well established that the reasonableness of a seizure turns on the nature and extent of interference with possessory, rather than privacy, interests."); *State v. Gardner*, 927 N.W.2d 84, 90 (N.D. 2019) ("This focus on privacy interests is central in determining whether a *search* is unreasonable, but it has little to do with whether a *seizure* is unreasonable."). Plaintiffs, of course, are not challenging the initial "heel prick or the test itself," FAC ¶ 2—just the continued retention, which they allege to be only a seizure, not a search, *id.* ¶¶ 164-74. For this seizure-only claim, the absence of a possessory interest is dispositive.

Finally, nothing about this argument means that the State can do whatever it wants with retained blood spots. Plaintiffs do not (and cannot) allege that DOH is "turning over blood to the Pentagon"—only that Texas has. *Id.* ¶ 66. Plaintiffs do

not (and cannot) allege that DOH is "selling the blood to third parties," *cf. id.* ¶ 60, or that there is any basis to believe that rDBS would be used to investigate or prosecute them or their children, *see id.* ¶¶ 49, 76. Rather, this case is about the closed set of three things DOH asserts a right to do with the residual spots: (1) follow-up testing for the child; (2) routine Lab QA/QC; and (3) developing new tests. *See* FAC ¶ 112. If Plaintiffs' imagined dystopian future ever *did* come to pass, then affected persons might well have claims to bring, depending on the facts. In today's world, however, Plaintiffs do not have a possessory interest in the blood that remains on the filter-paper card after Lab staff complete the initial (unchallenged) testing.

B. Any Seizure Is Reasonable Under The Special-Needs Exception.

"[T]he ultimate touchstone of the Fourth Amendment is 'reasonableness.'" *Brigham City v. Stuart*, 547 U.S. 398, 403 (2006). While one way to satisfy that requirement is to obtain a warrant based on probable cause, *United States v. Lewis*, 672 F.3d 232, 237 (3d Cir. 2012), a long-recognized exception to the warrant requirement is the "special needs" doctrine, which applies "when special needs, beyond the normal need for law enforcement, make the warrant and probable-cause requirement impracticable," *Griffin v. Wisconsin*, 483 U.S. 868, 873 (1987) (cleaned up); *see Ashcroft v. al-Kidd*, 563 U.S. 731, 736 (2011); *Nat'l Treasury Employees Union v. Von Raab*, 489 U.S. 656, 668 (1989) (recognizing that "the Government's need to discover [] latent or hidden conditions, or to prevent their development," can

at times justify "searches without any measure of individualized suspicion"). When the government argues that special needs justify a Fourth Amendment intrusion, "courts must undertake a context-specific inquiry, examining closely the competing private and public interests advanced by the parties." *Chandler v. Miller*, 520 U.S. 305, 314 (1997). And where, as here, the challenge is to a program as a whole, courts must balance the State interest underlying the program, and the extent to which the program "can reasonably be said to advance that interest," against the "degree of intrusion" caused by the program. *See Mich. Dep't of State Police v. Sitz*, 496 U.S. 444, 455 (1990); *see also Neumeyer v. Beard*, 421 F.3d 210, 214 (3d Cir. 2005) (constitutionality in such cases "'is judged by balancing [a State's] intrusion on the individual's Fourth Amendment interests against its promotion of legitimate governmental interests' beyond that of typical law enforcement"). Here, the degree to which retention advances public-health interests far outweighs any intrusion.

1. Retention Furthers Powerful Non-Law Enforcement Interests.

DOH's retention of residual blood spots benefits both the child tested and future children in numerous ways. And all of these interests, it bears emphasizing, have nothing to do with investigating crimes or any other enforcement regime.

Begin with the child itself. The State "has a compelling interest in the health" and "welfare" of children within its borders; indeed, "its obligations as parens patriae require the State to protect children's best interests." *Paul P. v. Verniero*, 982 F.

Supp. 961, 967 (D.N.J. 1997), *aff'd*, 170 F.3d 396 (3d Cir. 1999); *see also, e.g.*, *Santosky v. Kramer*, 455 U.S. 745, 766 (1982). Retention primarily benefits the individual child (and family) by allowing follow-up testing, whether to probe a potentially inaccurate initial result (whether a false positive or, more critically, a false negative), or because a late-onset disorder or medical advancements provide a basis for further analysis. Crucially, no one knows after "one to two weeks," FAC ¶ 166, if a particular child is going to need such follow-up testing—most classically, because a doctor comes to suspect that the initial result was either a "false positive" or, more critically, "false negative." It is *because* no one has such a crystal ball that New Jersey, like *all* States, does not destroy residual blood spots at the two-week mark in the absence of an express destruction request.

Then there are diseases that manifest later in infancy or toddlerhood. Take cytomegalovirus (CMV), a virus that can infect newborns at birth (*i.e.*, congenital CMV, or cCMV) without producing symptoms until later. *See* CDC, *About Cytomegalovirus*, https://tinyurl.com/mjbwah5n. Because *congenital* CMV is correlated with worse health outcomes, *see* Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 Ariz. L. Rev. 729, 760 (2019), testing *newborn* blood is important: looking at those samples is the only way to tell whether a CMV infection began at birth. So the State has a strong interest in ensuring that a sample of newborn blood still exists if a child begins showing symptoms of a late-onset-

manifestation disorder like cCMV. That interest is also strong with respect to disorders that the State does not yet screen for, because parents may then ask DOH to send a blood spot sample to a third-party lab for further testing—and the samples can also help the State develop new tests to add to its panel as research advances.

Here, too, cCMV is a good example. Testing for cCMV is not yet widespread; Minnesota became the first State to screen all newborns for it in February 2023, *see* Minnesota Department of Health, *Minnesota Becomes First State To Screen All Newborns For Congenital Cytomegalovirus* (Feb. 8, 2023), https://tinyurl.com/55rr5ypv, though New Jersey is not far behind, *see* N.J. Stat. Ann. 26:2-111.9(a) (requiring DOH to add a cCMV test to its panel once certain conditions are met) (eff. Jan. 18, 2022). Particularly where there is a late-manifesting disorder that New Jersey does not *yet* have the ability to screen for when a baby is born (as with cCMV), the State has a particularly strong interest in retaining residual spots to enable testing when a new test becomes available (whether by the State or a private lab), in the unfortunate event a child starts showing symptoms.

Retaining blood spots also benefits children and their families in other ways. In addition to having residual spots sent to another lab to test for a disease for which the State does not currently screen, parents can request that a residual blood spot be sent to a research institute in an attempt to find a cure for the disease from which their child suffers. Further, the information gleaned from testing—including, by

extension, testing a child's residual spots, in cases of false negatives or delayed-onset—can benefit other family members. Older siblings, for example, can make dietary changes if subsequent tests on a younger sibling's residual blood spots screen positive for certain disorders. Or if an older child had a false-negative result because of markers that fell just below the cut-off for positive diagnosis and suffered harms that could have been prevented with earlier detection—a younger sibling's doctor can draw on that information, for instance by advising the parents to start an immediate intervention if a younger child's markers likewise fall within a gray area.

Retaining residual spots is also critical to maintaining and improving the NBS program for all children. Information gleaned from false negatives, false positives, and late-onset manifestations is central to the program's mandate because it enables DOH to better calibrate its diagnostic tools for the population it serves, reducing the likelihood that it will miss conditions that could or should have been diagnosed at birth, or inaccurately diagnose conditions that were not in fact present. Looking back at a child's newborn blood is crucial for that learning process, because newborn blood differs from other blood—the presence and volume of certain biomarkers can vary greatly. Esan Ayodele Jacob, *Hematological Differences In Newborn and Aging*, 3 Hematology & Transfusion Int'l J. 178, 178 (2016); *see also* Maria A. Proytcheva, *Issues in Neonatal Cellular Analysis*, 131 Am. J. Clin. Pathol. 560, 560 (Apr. 2019) (agreeing that metrics at birth "differ significantly").

Analyzing past results is not just good science, but also legally required, since both state and federal law require adequate QA/QC in NBS programs. *See* 42 U.S.C. § 263a(b), (c)(2), (f)(1)(A); N.J. Stat. Ann. § 26:2-111. The Lab, for instance, must comply with numerous regulations that require the testing of de-identified positive and negative samples to ensure the system's integrity. *See, e.g.*, 42 C.F.R. §§ 493.1200, .1253, .1255, .1256, .1282. But the Lab cannot meet these mandates without residual spots from New Jersey babies. Even assuming for present purposes that synthetic materials can sufficiently mimic newborn blood as a general matter, *cf.* FAC ¶¶ 127-129, federal regulations require that the Lab perform QA/QC tests on its "patient population," 42 C.F.R. § 493.1282(b)(1)(iii); *see also id.* §§ 493.1253(b)(1)(iii), 493.1256(d)(3). Since the Lab screens all newborns, its "patient population" is comprised of babies born in the State each year. If the Lab cannot count on a robust, broad-based range of samples that represents the genuine demographics of the State, then QA/QC cannot be adequately performed on its patient population.

To be clear, retaining a broad-based population of residual blood spots does not just help prevent NBS tests from getting worse—it also helps them get better. Lab cut-off levels are not static. As new diagnoses and data come to light, as when new false-positives and false-negatives are detected, the Lab can revisit and potentially tweak where it sets those lines. There are instances, such as when testing

methods change, when positive bloodspot samples are necessary[17]—which again may explain why *no* State destroys samples at two weeks absent an express request for retention, as Plaintiffs demand.

By the same token, retaining rDBS allows for the development and validation of *new* tests. Many of the disorders that the Lab screens for are (thankfully) rare, and there are others for which no test currently exists. Watson et al., *The Progress and Future of US Newborn Screening*, 8 Int. J. Neonatal Screen. 41 (2022). By examining the residual spots of children who have suffered from a given condition (including later in childhood), labs can look for markers of that condition and then develop a new test that screens for those markers, allowing future newborns to be more rapidly diagnosed and more effectively treated. But these advancements are possible only if the newborn spots still exist—which is why States have such strong interests in ensuring that they do.

Finally, there are compelling reasons to use an "opt-out" for some period of retention after the initial testing is complete—as underscored by the fact that *no* State imposes the default-destruction model that Plaintiffs demand. As noted, "context" matters in assessing the reasonableness of DOH's default-rule under the special-needs rubric. *Chandler*, 520 U.S. at 314. And as an initial matter, the State has its

[17] *See, e.g.*, W. Harry Hannon et al., *Using Tandem Mass Spectrometry for Metabolic Disease Screening Among Newborns* (Apr. 2001), CDC, https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5003a1.htm.

own obligations to care for the wellbeing of children born within its borders, and thus may reasonably factor in the benefits just detailed. *See supra* at 26. Moreover, the State is not preventing parents from making "the 'wrong' choice," FAC ¶ 8, because parents *do* have a choice—the question is whether two years of retention is a permissible default rule, from which any parent can opt out (and thus disregard DOH's opinion that retention is good). *See* Noor Giesbertz et al., *A Thick Opt-Out Is Often Sufficient*, 13 Am. J. Bioethics, 44, 45 (Apr. 2013) (recognizing that "public trust and respect for autonomy can be safeguarded within an opt-out procedure"). Plaintiffs simply offer a competing default: destruction at two weeks.

The context underscores why the State's default is reasonable. The NBS program operates through the hospitals and birthing centers within the State. FAC ¶¶ 17, 92. The logistics involved are significant, and the program depends on hospital staff who do not work for DOH, and who juggle much more than just the NBS program in the first 24-48 hours of a child's life. *See id.* Under the default-destruction rule Plaintiffs urge, if hospital staff misplace a form, or if the parent is exhausted and forgets to timely request retention, DOH would destroy the sample once the baby turned two weeks old. And that destruction would, of course, be irreversible: a doctor who wanted to test the baby's newborn blood in four or

fourteen months—*e.g.*, to assess a possible cCMV diagnosis—could never do so.[18] By contrast, DOH's destruction-on-request default carries no such risk: if a couple forgets to request destruction initially and only remember once their child stops waking up four times a night, the worst that will have happened is presumably that the sample will have sat in a "storage box[]" for a few extra weeks. FAC ¶ 37. There are thus go reasons no State has ever adopted the default that Plaintiffs favor.

2. Any Intrusion On Plaintiffs' Interests Is Minimal.

The reasons for initial retention of rDBS absent a destruction request far outweigh any intrusion on Plaintiffs. For one, if Plaintiffs do not want DOH to retain the residual spots, they simply have to say so. Courts regularly count a person's ability to avoid a special-needs search or seizure as a key factor in upholding such actions, *e.g.*, *United States v. Martinez-Fuerte*, 428 U.S. 543, 559 (1976) (finding seizure reasonable where motorists are "not taken by surprise as they know, or may obtain knowledge of, the location of checkpoints"); *Wyman v. James*, 400 U.S. 309, 320 (1971) (finding putative search reasonable where, among other things, plaintiff "received written notice several days in advance of the intended home visit"), which underscores that any seizure that one can easily "opt out" of is hardly a serious

[18] Indeed, destroying the sample unless the parent affirmatively requests retention within the first two weeks of the child's life is problematic on Plaintiffs' own logic—they themselves emphasize that parents are typically "overwhelmed" at this time. *See* FAC ¶ 94 (quoting *Kanuszewski*, 684 F. Supp. 3d at 647).

intrusion. *See also* Cass R. Sunstein, *Deciding by Default*, 162 U. Pa. L. Rev. 1, 5 (2013) ("When private or public institutions establish a default rule, they do not force anyone to do anything. … Whether people must opt out or opt in, they are permitted to do so as they see fit."); *supra* at 13-16. And Plaintiffs do not (and cannot) dispute that New Jersey leaves the choice to parents—if they want to obtain destruction after initial testing, they can easily exercise that option. *See* FAC ¶¶ 88-89.[19]

For another, even where individuals choose (like Plaintiffs) not to opt out of initial retention, the character of any "seizure" is virtually always that the spots simply sit in a secure government facility for about 102 weeks following initial testing. *See also* N.J. Stat. Ann. § 26:2-111 (requiring Lab to protect confidentiality); 42 C.F.R. §493.1231 (same).[20] Given that, in other special-needs contexts, the Supreme Court has described the "character of the intrusion" of forcing students to

[19] Tellingly, Plaintiffs laud Virginia for giving parents "the option," at birth, "to have the hospital collect and give parents a sample of the newborn's blood," FAC ¶ 106, but overlook that New Jersey gives parents an analogous option to diverge from the default. And they miss that Virginia's default, like New Jersey's, does *not* treat parental silence as requiring destruction of residual spots after two weeks. *See* Va. Dep't of Health, *Retention of Residual Dried Blood Spots* (Nov. 8, 2016), https://www.vdh.virginia.gov/dried-blood-spot-newborn-screening/retention-of-residual-dried-blood-spots. Further, Plaintiffs miss that the option provided to parents in Virginia to receive a sample of their child's blood is completely different from, and occurs in addition to, the collection and retention for newborn screening. *Compare* Va. Code Ann. § 32.1-134.02, *with* Va. Code Ann. § 32.1-65.

[20] To the extent the spots are used for QA/QC purposes or for new-test development, meanwhile, DOH de-identifies those spots before performing any such analysis, *see* New Policy, further minimizing the putative intrusion.

urinate for suspicionless drug tests while a monitor stands nearby as "negligible," *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 658 (1995); *see Bd. of Educ. of Indep. Sch. Dist. No. 92 of Pottawatomie Cnty. v. Earls*, 536 U.S. 822, 832-33 (2002) (same), it cannot be that the mere storage of those spots in a secure facility for just under two years is a significant intrusion. And, further underscoring the reasonableness of the challenged program, the default flips at two years: if DOH has not heard anything in two weeks, it retains the spots, but if it has not heard anything after two years, it destroys them. *E.g.*, FAC ¶ 96. That is exactly the kind of balanced approach the special-needs exception requires in this public-health context.

Any risk of disclosure to others during the two-year default period, meanwhile, is minimal. *See supra* at 17-19. With respect to research institutions, such disclosure is both rare and subject to other protections. As noted, federal law already requires federally-funded institutions to obtain express, informed consent for any research on rDBS linked with a child's identifying information, and New Jersey has extended this requirement to all research institutions. *See supra* at 9. Thus, New Jersey does not allow any identified samples to be provided for research purposes without express, informed consent for the particular research to be undertaken.

The risk that residual blood spots will be released to law enforcement, meanwhile, is (as also noted) extremely low, and regardless gives no basis to invalidate any aspect of the program. Babies are (of course) not targets of criminal

investigations, and even under the old (longer) retention policy, litigation revealed only five uses, FAC ¶ 49—hardly enough to change the analysis of a program that serves 100,000 newborns per year. *Cf. Earls*, 536 U.S. at 833 (explaining, in disregarding alleged example of choir teacher leaving prescription-drug lists in view of other students that "[t]his one example of alleged carelessness hardly increases the character of the intrusion" in rural school district's policy). And Directive 2024-03 now *ensures* that law enforcement will be able to seek such information only "in genuinely exceptional circumstances," and even then only with a warrant or its equivalent (except, as explained, in trying to identify a missing child or unknown body). *See* AG Directive. In other words, for parents who do *not* opt-out, even assuming a law-enforcement entity in the State wishes to use a residual spot to try to arrest or prosecute someone, the only way it could do so within the initial two-year retention window is by obtaining both (1) clearance from the Attorney General's office and (2) a warrant or its "functional equivalent," *see Dyal*, 478 A.2d at 396. None of that suggests a significant intrusion—and, again, if parents wish to foreclose any possible risk, all they have to do is request destruction.

Indeed, the complaint's handful of alleged examples and hypotheticals—drawn almost entirely from other States, *see* FAC ¶¶ 48-52, 60, 64-66—is dramatically mismatched with the scope of relief they seek. "For a host of good reasons, courts usually handle constitutional claims case by case, not en masse."

Moody v. NetChoice, *LLC*, 144 S. Ct. 2383, 2397 (2024). Instead, when faced with broadscale challenges like this one, they focus on the circumstances in which the challenged policy is "most likely to be constitutional," rather than on "hypothetical scenarios" that "might raise constitutional concerns." *United States v. Rahimi*, 144 S. Ct. 1889, 1903 (2024). Even if that were not so, many of the FAC's hypotheticals are facially implausible in the first place. *Cf. Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). And where they are not—*e.g.*, if a future criminal defendant ever finds himself facing prosecution based on information derived from the NBS program—the answer is for that person to seek as-applied relief (presumably via a motion to suppress), not for a court to redesign the entire program prophylactically. *See Moody*, 144 S. Ct. at 2397. Thus, Plaintiffs' hypotheticals should receive little if any weight in applying the special-needs balancing test to this public-health program. And because that balance already weighs heavily in favor of allowing the State to retain residual blood spots for the first two years of the child's life absent a request for destruction, this Court should dismiss Plaintiffs' outlier attack on DOH's crucial—and entirely mainstream—public-health program.

III. THE PARENTS' DUE PROCESS CLAIM FAILS AS A MATTER OF LAW.

DOH's default retention policy does not implicate any fundamental right of the Parent-Plaintiffs. Whether conceived of as a failure to state a claim or a failure to articulate an injury-in-fact (or both), this claim likewise merits dismissal.

Nothing about the State's default two-year retention policy burdens a parent's substantive due process "right to direct the care, custody, and control of their children." FAC ¶ 185. The Fourteenth Amendment's Due Process Clause protects only those unenumerated rights that "are, objectively, deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty." *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (cleaned up). No one disputes that parents have rights to direct the upbringing of their children, but the FAC reveals no basis to conclude that these rights extend as far as forcing the State to obtain express consent before retaining residual blood spots for two years after the initial heel prick and testing that Plaintiffs themselves do not challenge.

Tellingly, the complaint cites only two cases in support, and both are far afield. *See* FAC ¶¶ 186-87 (relying on *Troxel v. Granville*, 530 U.S. 57 (2000) (plurality op.) and *Gruenke v. Seip*, 225 F.3d 290 (3d Cir. 2000)). *Troxel* involved a parent's right to exclude grandparents from visiting grandchildren, despite a state statute permitting a petition for court-ordered visitation. 530 U.S. at 60, 68. But DOH's program does not involve Lab workers demanding to interact with the Children in any way—the alleged intrusion here is simply keeping the residual spots in "storage boxes." FAC ¶ 37. And *Gruenke* involved a school coach whose prominent efforts to coerce a student into taking a pregnancy test intruded "into what was a private family matter," preventing the parents from handling their teenage

daughter's pregnancy as they said they otherwise would have. 225 F.3d at 295, 306. But DOH maintains strict confidentiality around NBS results (as it must), N.J. Stat. Ann. § 26:2-111; 42 C.F.R. §493.1231, and in any event, Plaintiffs are *not* challenging "the test itself," FAC ¶ 2. That dooms the analogy, because there is no medical procedure that is compelled, or family decision that is plausibly usurped, by retaining residual blood spots in a government facility until a child's second birthday. And any parent bothered by that two-year retention period can, of course, avoid it simply by asking.[21]

Indeed, not only do the Parent-Plaintiffs fail to state a claim, but they also fail to articulate an injury-in-fact. To invoke Article III jurisdiction, plaintiffs must show that the complained-of government action harms them "in a personal and individual way" that is "real and not abstract," and "actual or imminent, not speculative." *All. for Hippocratic Med.*, 602 U.S. at 381. But the FAC leaves unsaid how retaining the spots for up to two years interferes with the Parents' rights to direct the upbringing of their children. For example, they allege that retention interferes with their rights to "make medical decisions for their children," FAC ¶ 187; *see also id.* ¶ 195, but

[21] If the Court found that Parents had some legally protected interest in the Children's residual blood spots that falls short of a fundamental right, then the proper standard of review would be rational basis. *See Child. Health Def., Inc. v. Rutgers, the State Univ. of N.J.*, 93 F.4th 66, 78-81 (3d Cir. 2024). But, as explained above, *see supra* at 26-33, DOH's policy would satisfy any level of scrutiny given the compelling needs it serves and its narrowly tailored methods.

do not identify any medical decision impacted. And as already explained, relying on hypotheticals about how a government could "possibly use" residual spots "against the children," FAC ¶ 76, falls far short of rendering an alleged injury "actual or imminent," *All. for Hippocratic Med.*, 602 U.S. at 381, rather than just an "academic exercise in the conceivable," *Thorne v. Pep Boys Manny Moe & Jack, Inc.*, 980 F.3d 879, 893 (3d Cir. 2020) (quotation omitted). On either basis, Count II fails.

CONCLUSION

This Court should dismiss Plaintiffs' First Amended Complaint.

Respectfully submitted,

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Dated: September 9, 2024